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DEC 27 1993

Re: Betaseron®  
Docket No. 93E-0353

The Honorable Bruce Lehman  
Assistant Secretary of Commerce and  
Commissioner of Patents and Trademarks  
Washington, D.C. 20231

Dear Commissioner Lehman:

This is in regard to the application for patent term extension for U.S. Patent No. 4,588,585, filed by Cetus Oncology Corporation, under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Betaseron®, the human biological product claimed by the patent.

The total length of the regulatory review period for Betaseron® is 3,720 days. Of this time, 3,319 days occurred during the testing phase and 401 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: May 19, 1983.  
The applicant claims April 4, 1986, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was May 19, 1983, which was thirty days after FDA receipt of the IND.
2. The date the application was initially submitted with respect to the human drug product under section 351 of the Public Health Service Act: June 18, 1992.  
The applicant claims June 16, 1992, as the date on which the Product License Application (PLA) was initially submitted. However, FDA records indicate that the PLA was initially submitted on June 18, 1992.
3. The date the application was approved: July 23, 1993.  
FDA has verified the applicant's claim that PLA No. 92-0495 was approved on July 23, 1993.

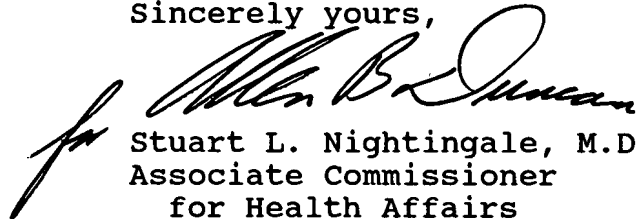
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This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

  
Stuart L. Nightingale, M.D.  
Associate Commissioner  
for Health Affairs

cc: Anthony J. Zelano, Esq.  
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